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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,043	06/27/2003	Darin G. Schaeffer	10703/025	7932

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INDIANAPOLIS OFFICE 27879
BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204-2033

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,043

Applicant(s)

SCHAEFFER ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 34-36, 38, 41-46, 48, 50-51 is/are rejected.
- 7) ☒ Claim(s) 33, 37, 39, 40, 47, 49, 52, 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group III (claims 29-53) in the reply filed on 1/25/07 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner because all claims were considered in the previous office action. This is not found persuasive. Although all claims were considered in the previous office action but the restriction is still proper because each group of invention are independent or distinct from the reasons given in the restriction mailed on 12/14/06 and the inventions have acquired a separate status in the art due to their recognized divergent subject matter. The divergent subject matter of the inventions imposed a serious burden on the examiner if restriction is not required.

Note: The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 29-32, 34, 38, 46, 48, 50, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (4,271,839). Fogarty et al. disclose:

Regarding claim 29, a sheath comprises a folded portion (20b, fig. 7) when the sheath is in a non-expanded condition and an extended portion (20b, fig. 8) when the sheath is in a radially expanded condition, an insertion member (14 or 22b).

Regarding claim 30, a handle (24/26)

Regarding claim 31, the insertion member (14) is a cannula having an inner lumen and a pusher member (22b)

Regarding claim 32, the handle (26) comprise a perimetrical opening

Regarding claim 34, the sheath body comprises a low friction non-rigid material

Regarding claim 38, the handle (24) comprises ring member/handle (26) for engaging the sheath to the handle.

Regarding claim 46, an introducer sheath comprises a folded portion (20b, fig. 7) when the sheath is in a non-expanded condition and an extended portion (20b, fig. 8) when the sheath in a radially expanded condition, an insertion member (14 or 22b), a dilator (32,38).

Regarding claim 48, a pusher mechanism (22b)

Regarding claim 50, a handle (24,26)

Regarding claim 51, handle member (26) having perimetrical opening.

4. Claims 29, 30, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Aboul-Hosn (5,741,234). Aboul-Hosn discloses a sheath (10) having a folded portion (26), an insertion member (24, 14, see fig. 2 and 3).

5. Claims 41, 42, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Heck (6,083,207).

Heck disclose a sheath (20) having an axial opening for passage of dilator (300) and a handle (18) engaged with the sheath, the handle having an axial opening aligned with the sheath axial opening for passage of the dilator (300, see fig. 1), the handle

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further including a perimetrical opening (between two section 114, 116) for removing the sheath from the dilator.

Regarding claim 42, the handle (18) has a C-shaped (fig. 4) and a circumferential opening (36, fig. 5).

Regarding claim 45, a hemostatic valve member (12).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heck '207 in view of Osborne (4,306,562). Heck discloses all the limitations of the claims except fails to disclose the material of the sheath, as claimed. The material of the sheath as claimed is well known in the art for making introducer sheath for example, Osborne discloses a splittable introducer sheath being made from flexible low friction material polytetrafluoroethylene (see claim 3 of the Osborne reference). Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to make the sheath as disclosed in Heck reference from polytetrafluoroethylene or provide a sheath to use with Heck's system wherein the sheath being made from

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polytetrafluoroethylene since the sheath being made from polytetrafluoroethylene is biocompatible and flexible such that it would be easily inserted into a body lumen.

8. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (4,271,839) in view of Osborne (4,306,562). Fogarty et al. discloses all the limitations of the claims except fails to disclose the material of the sheath, as claimed. The material of the sheath as claimed is well known in the art for making introducer sheath for example, Osborne discloses an introducer sheath being made from flexible low friction material polytetrafluoroethylene (see claim 3 of the Osborne reference). Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to make the sheath as disclosed in Fogarty reference from polytetrafluoroethylene since the sheath being made from polytetrafluoroethylene is biocompatible and flexible such that it would be easily inserted into a body lumen.

Allowable Subject Matter

9. Claims 33, 37, 39, 40, 47, 49, 52, 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

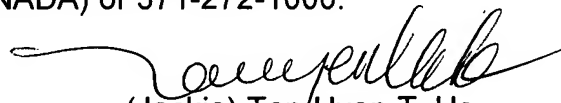
Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

April 26, 2007